



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: May 4, 2016

SUBJECT: Response to Deficiencies in Support of the Registration of Stimulate Yield Enhancer Plus with 0.005% Gibberellic Acid, 0.009% Cytokinin as kinetin, and 0.005% Indole-3-butyric acid as its Active Ingredients

Type of Data Review:	Product Chemistry
Decision Number:	511210
DP Number:	433294
EPA File Symbol Number:	57538-LG
Chemical Class:	Biochemical
PC Code:	116801, 043801, 046701
Tolerance Exemptions:	40 CFR § 180.920, 180.940
MRID Nos.:	49887800-01

FROM: Sadaf Shaukat, Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Angela Gonzales, Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Cody Kendrick, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

This is a response to deficiencies for Stoller Enterprises Inc. who submitted an application for the end-use product (EUP) 57538-LG, with 0.005% Gibberellic Acid, 0.009% Cytokinin as kinetin, and 0.005% Indole-3-butyric acid (IBA) as its active ingredients. They submitted new product chemistry data in a package dated 3/28/16. This PGR product promotes plant growth by stimulating cell division, cell differentiation and enlargement, nutrient uptake, and nutrient utilization. It is used on agriculture, ornamentals, golf courses, transplants, and seed treatment. In addition, the registrant has created a sublabel for homeowner garden use.

The registrant addressed the following deficiencies by submitting acceptable product identity and composition data, along with an acceptable 1-year storage stability/corrosion characteristics study. . In addition, the storage stability and corrosion characteristics study performed on Fruit Sizer Plus (Reg. #57538-LT) was submitted and will bridge the requirement for this product. After review of the registrant's submission, no deficiencies remain.

- a) *Box 8 (pH) must be filled on the CSF.*
- b) *The registrant did not address the following product chemistry data requirements (OCSPP 880.1100, 880.1200, 880.1400). The registrant must satisfy these data requirements.*
- c) *The registrant addressed the physical and chemical characteristics data requirements with an acceptable self-certified form.*
- d) *The registrant attempted to fulfill the storage stability and corrosion characteristics data requirement by citing an accelerated storage study, however this study is not acceptable to BPPD in lieu of the 1-year storage stability study.*

STUDY SUMMARIES

Product Chemistry (MRID 49887801)

Test Material: Cytokinin (as Kinetin), Gibberellic Acid, IBA

- I. **PRODUCT IDENTITY AND COMPOSITION (OCSPP 880.1100):** This application is for an end-use product called Stimulate Yield Enhancer Plus. This PGR product promotes plant growth by stimulating cell division, cell differentiation and enlargement, nutrient uptake, and nutrient utilization. It is used on agriculture, ornamentals, golf courses, transplants, and seed treatment. In addition, the registrant has created a sublabel for homeowner garden use. The active ingredients in this product (w/w) are 0.005% Gibberellic Acid, 0.009% Cytokinin as kinetin, and 0.005% Indole-3-butyric acid (IBA). The inert ingredients (w/w) are included in the confidential attachment. The CSF and product label are in agreement regarding the content of active ingredient in the product. The active ingredient name given on the product label matches the name given on the CSF. The CAS Nos. for the active and inert ingredients are provided on the CSF. The density, pH, and flash point boxes on the CSF are filled in, and the CSF is signed.
- II. **DESCRIPTION OF STARTING MATERIALS AND FORMULATION PROCESS (OCSPP 880.1200):**
A description of the starting materials and formulation process was provided in the registrant's latest submission dated 3/28/16. The registrant described the quality control measures taken during the process.
- III. **DISCUSSION OF FORMATION OF IMPURITIES (OCSPP 880.1400):** A discussion of the formation of impurities was provided in the registrant's latest submission dated 3/28/16.

1-year Storage Stability- OCSPP 830.6317: ACCEPTABLE (MRID 49887801)

Sampling Interval	Mean% Gibberellic Acid
Initial	0.0032
6 Months	0.0033
12 Months	0.003

Sampling Interval	Mean% Kinetin
Initial	0.0251
6 Months	0.0250
12 Months	0.0252

Sampling Interval	Mean% IBA
Initial	0.0094
6 Months	0.0093
12 Months	0.0091

Sampling Interval	Mean% IAA
Initial	0.0061
6 Months	0.0061
12 Months	0.006

1-year Corrosion Characteristics- OCSPP 830.6320: ACCEPTABLE

Sampling Interval	Visual Observations
Initial	Liquid; clear light yellow
6 Months	Liquid; clear light yellow
12 Months	Liquid; clear light yellow

ANALYTICAL METHODS: HPLC with UV detection. For additional details regarding analytical methods, sample preparation, validation, and calculations see Report Number 00003-87-4A.

CONCLUSIONS: All four active ingredients in Fruit Sizer Plus (57538-LT) were stable over the 12-month testing period. Corrosion and/or physical/color changes were not noted in/on any of the containers.

NOTE TO RAL: Please see science review dated 3/1/16 for study summaries of other product chemistry data, including physical and chemical characteristics.

Inert ingredient information may be entitled to confidential treatment

CONFIDENTIAL ATTACHMENT

STUDY SUMMARIES

Note: The registrant is revising the formulation of an older product and is replacing the inert ingredient

Product Chemistry

TABLE 1. Nominal CSF concentrations and certified limits for Stimulate Yield Enhancer Plus					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Gibberellic Acid	043801	Active Ingredient	0.005	0.0045	0.0055
Cytokinin as Kinetin	116801	Active Ingredient	0.009	0.008	0.01
IBA	046701	Active Ingredient	0.005	0.0045	0.0055
Inert Ingredients					

^aData from CSF